



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

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Secretary

MONICA BHAREL, MD, MPH
Commissioner

Tel: 617-624-6000
www.mass.gov/dph

August 31, 2015

Alternative Therapies Group, Inc.
Mr. Christopher Edwards
24 R. Pleasant St., Unit 2
Newburyport, MA 01950

Re: Request for an Expanded Waiver

Dear Mr. Edwards:

On July 31, 2015, Alternative Therapies Group ("ATG") submitted a written request to expand the existing waiver granted to ATG on June 19, 2015 ("June Waiver") from 105 CMR 725.105(C)(2)(a) as it applies to heavy metals and pesticides, and 105 CMR 725.105(E)(2)(g), for finished plant material to also allow the dispensing of cannabis concentrate. In that expanded waiver request, you submitted documentation that two samples of cannabis concentrate were tested and met the standard as outlined in the *Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-Infused Products for Massachusetts Registered Medical Marijuana Dispensaries*, with the exception of cadmium. In your expanded waiver request, you also represented that the single Massachusetts laboratory currently available to conduct testing on marijuana products "still cannot test for cadmium at the necessary detection limit." The June Waiver was granted partly in response to a request for a waiver from 105 CMR 725.105(E)(2)(g), which only applies to finished plant material. DPH deems the request for an expanded waiver to include a request for a waiver from 105 CMR 725.105(E)(3)(i), which applies to marijuana-infused products.

I find that compliance would cause undue hardship to ATG and patients, that ATG will institute compensating features acceptable to the Department of Public Health (the "Department") and that with those compensating features, non-compliance does not jeopardize the health or safety of any patient or the public. ATG's July 31, 2015 request for an expanded waiver from 105 CMR 725.105(C)(2)(a), only as it applies to heavy metals and pesticides, is granted to allow the dispensing of cannabis concentrate, with the following conditions. Please note that the June Waiver remains in effect except where expanded by the following conditions, in which case the following conditions apply:

1. For the remainder of the Waiver Term as stated in the June Waiver, or until such time that ATG has demonstrated to the Department's satisfaction that it can fully comply with

the *Protocol for Sampling and Analysis of Environmental Media for Massachusetts Registered Marijuana Dispensaries* and *Protocol for Sampling and Analysis of Finished Medical Marijuana Products and Marijuana-Infused Products for Massachusetts Registered Medical Marijuana Dispensaries* (collectively, the “Protocols”), whichever occurs earlier, it may only dispense a maximum of 23.3 grams of cannabis concentrate (equivalent to 4.23 ounces of finished plant material) to any qualifying patient or caregiver for their sixty-day supply and must supply each qualifying patient or caregiver with instructions that a maximum of 1.13 grams of cannabis concentrate may be consumed per day;

2. During the Waiver Term, ATG shall continue to conduct testing in compliance with the Protocols for finished plant material and cannabis concentrate for all substances listed in 105 CMR 725.105(C)(2)(a), including heavy metals and pesticides, and submit the results to the Department;
3. During the Waiver Term, ATG shall take all necessary steps to ensure that the presence of heavy metals in finished plant material and cannabis concentrate is as minimal as possible, but shall not be required to meet the levels specified in Exhibit 4 of Section 7 of the *Protocol for Sampling and Analysis of Finished Medical Marijuana and Marijuana-Infused Product for Massachusetts Registered Marijuana Dispensaries*;
4. Consistent with ATG’s representation in its request that it does not use the plant-growth regulators and pesticides identified in the Protocol, ATG shall not use any of the plant-growth regulators and pesticides identified in the Protocol during the Waiver Term;
5. During the Waiver Term, ATG shall be subject to increased inspections to ensure compliance with the conditions of this waiver, including requests for additional testing and information regarding the testing capabilities of any independent laboratory selected for testing by ATG;
6. ATG must maintain records available for inspection by the Department that it only dispenses a maximum of 23.3 grams of cannabis concentrate (equivalent to 4.23 ounces of finished plant material) to any qualifying patient or caregiver for their sixty-day supply and that each qualifying patient has received the instructions that a maximum of 1.13 grams of cannabis concentrate may be consumed per day;
7. Labels for all marijuana finished plant material and cannabis concentrate produced during the Waiver Term shall disclose that product may not meet the established standards for heavy metals and pesticides:

“WARNING: This product may not meet the established standards for heavy metals and pesticides.”

8. The Department reserves the right to revoke or modify this waiver at any time should it determine that ATG, or any of its dispensary agents, fail to comply with the terms and

conditions of the waiver, or if the Department finds that the waiver no longer serves the interests of the public health or safety.

The Department anticipates that ATG will work expeditiously to resolve the issues that have led to the request for an expanded Waiver. If, however, ATG determines it cannot do so within the Waiver Term, a request for any additional waiver must be received by the Department 14 days prior to the expiration of the current waiver. Please contact RMDcompliance@state.ma.us with any questions regarding this waiver.

Sincerely,

A handwritten signature in blue ink, appearing to read 'MBne', is positioned above the printed name.

Monica Bharel, MD, MPH
Commissioner
Massachusetts Department of Public Health